

Application Serial No. 07/044,719, filed May 1, 1987. Finally, Applicant has not abandoned this application, nor has he filed an Appeal Brief. Accordingly, Applicant has satisfied the requirements of § 1.129(a).

AMENDMENTS

Please amend this application as follows:

IN THE CLAIMS:

Please cancel claims 80, 85-95, and 97-103, without prejudice or disclaimer, and amend claim 72 as follows:

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- ~~72. (Twice Amended) A method of transferring a gene into a recipient subject, comprising:~~
- (a) ~~transfected somatic cells *in vitro* with a DNA sequence by chemical or physical techniques [and without using a viral vector] to introduce the DNA sequence into the cells[, wherein the DNA sequence comprises no DNA of retroviral origin, wherein the DNA sequence comprises the gene and a promoter operably linked to the gene];~~
- (b) ~~screening the resulting transfected somatic cells *in vitro* to select a cell, wherein the selected cell is stably transfected with the DNA sequence by integration of the DNA sequence into the chromosome of the selected cell or in a replication competent plasmid to impart to the selected cell the permanent capacity to direct expression of the DNA sequence [possessing desired expression properties];~~
- (c) ~~cloning and expanding the selected somatic cell *in vitro*; and~~

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(d) [administering] injecting the resulting cloned and expanded cells [to] into the recipient subject;

wherein the DNA sequence comprises the gene and a promoter, wherein the promoter is not a retroviral promoter; and

wherein, following injection into the recipient subject, the clonal cells are incapable of causing recombination of the DNA sequence with endogenous retroviral sequences and initiating chronic viral infection in the recipient subject.

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Please add new claims 104-106 as follows:

--104. A method of for transferring a gene into a recipient subject, comprising:

(a) providing somatic cells;

(b) transfecting said somatic cells *in vitro* with a DNA sequence comprising said gene and a promoter capable of functioning in said somatic cells, wherein said gene encodes a gene product, and wherein said somatic cells are stably transfected with said gene by integration of the gene into the chromosomes of the somatic cells or in replication competent extrachromosomal plasmids to impart to said somatic cells the permanent capacity to direct expression of said gene upon induction of said promoter;

(c) screening the resulting transfected somatic cells *in vitro* to select a transfected somatic cell, wherein said screening comprises characterizing said transfected somatic cell with respect to expression and regulation of the gene by assaying for translation of the mRNA into the gene product;

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- (d) cloning and expanding, *in vitro*, the transfected somatic cell selected in step (c) to form 10^5 - 10^{10} transfected somatic cells;
- (e) combining the 10^5 - 10^{10} transfected somatic cells with a physiologically acceptable buffer or carrier; and
- (f) injecting the resulting transfected cell preparation into the recipient subject, wherein, following injection into the recipient subject, the clonal cells are incapable of causing recombination of the DNA sequence with endogenous retroviral sequences and initiating chronic viral infection in the recipient subject.

105. The method of any one of claims 72 or 104, wherein the transfected gene encodes human growth hormone.

106. The transfected cell preparation of any one of claims 72 or 104, wherein the transfected gene encodes insulin.--

REMARKS

Applicant has canceled claims 80, 85-95 and 97-103, without prejudice or disclaimer, amended claim 72, and added new claims 104-106. Upon entry of this amendment, claims 72-79, 82-84, and 104-106 will be pending in this application.

As Applicant discusses below, Applicant has canceled claims 80, 85-95, and 97-103 to reflect the amendments to claim 72. Applicant reserves the right to present claims to the subject matter of claims 80, 85-95, and 97-103 in this or another application.